

EXHIBIT 1

CONFIDENTIAL EXHIBIT

EXHIBIT 2

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EXHIBIT 3

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EXHIBIT 4



Office of Public Health Emergency Preparedness
Office of Research and Development Coordination
Washington, D. C. 20201

Request for Proposal (RFP) Number DHHS-ORDC-V&B - 05-06

Date: August 15, 2005

To: Prospective Offeror

Re: Acquisition of Smallpox MVA Vaccine for the Strategic National Stockpile

Dear Prospective Offeror:

The Department of Health and Human Services (DHHS) is seeking proposals from Offerors for the acquisition of 20 million doses (in single-dose vials) of MVA vaccine for the Strategic National Stockpile. The RFP also contains options for maintaining cGMP capability (warm base), the purchase of additional quantities of vaccine, and obtaining data to support expanded clinical usage. The contract period of performance is five (5) years, and the contract options would extend the contract period of performance by an additional 5 years.

This RFP is posted on the General Services Administration's (GSA's) Federal Business Opportunities Internet website also known as FedBizOpps Electronic Posting System (www.FedBizOpps.gov). For use by prospective Offerors, any amendments to this RFP shall also be posted on the same internet website. No other notice shall be given to prospective Offerors and it is incumbent on Offerors to make periodic inquiries.

Prospective Offerors are advised that DHHS is operating under stringent security requirements applied to all incoming mail and packages. This includes all proposals submitted under DHHS solicitations by regular mail, express mail delivery, or hand-delivered directly by an offeror or by a courier service. Please note that personal identification of couriers or Offerors is required for delivery of proposals.

In accordance with the attached RFP, Offerors are required to submit the original, twenty (20) copies, and twenty (20) electronic copies on a CD ROM or USB drive of their technical proposals, and the original, ten (10) copies, and five (5) electronic copies on a CD ROM or USB drive of their business proposals. The proposals must be received by the Contracting Officer no later than **September 29, 2005, at 3:00 PM local time** at the address listed in Section L of the RFP.

Any questions concerning the RFP should be submitted in writing to Ms. Brenda Brooks, Contract Specialist, no later than **August 29, 2005** at the address specified below and marked "Offerors Questions, RFP-DHHS-ORDC-V&B-05-06". You may also email your questions to Brenda.Brooks@hhs.gov. Any questions and answers will be made available through an amendment to the RFP posted to the FedBizOpps.

Letters of Intent to submit a proposal must be received by **September 5, 2005**. Section J of the RFP contains a copy of the Proposal Intent Response Sheet. Proposals will be accepted in lieu of letter of intent. Please note that your expression of intent is not binding but will greatly assist us in planning for the proposal evaluation process.

Please be advised of the following **Critical Dates:**

*Submission of questions/comments on RFP	August 29, 2005
Letters of Intent to Propose	September 5, 2005
Proposal Due Date	September 29, 2005

Please direct all questions to Ms. Brenda Brooks on (301) 435-2765.

Department of Health and Human Services

By: /S/
Sharon M. Kraft
Contracting Officer
HHS/OS/OPHEP/ORDC
6700-B Rockledge Drive
Room 4119
Bethesda, MD 20817

U.S. Department of Health and Human Services
Office of the Assistant Secretary
Office of Public Health Emergency Preparedness
Office of Research and Development Coordination
RFP-DHHS-ORDC-V&B-05-06
Acquisition of MVA Vaccine for the Strategic National Stockpile

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.fedbizopps.gov/		
2. SECTION A – SOLICITATION/CONTRACT FORM – OMB No. 0990-0115 NOTE: The issuance of this solicitation does not commit the government to an award.		
3. Issue Date: August 15, 2005	4. Due Date: September 29, 2005 Time: 3:00 PM , EST	5. Small Bus. Set-Aside: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS: 325414 (See Part IV, Section L.)
6. Proposal Delivery Information See Section J	7. Number of Awards: <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards* *1-2 awards	8. Technical Proposal Page Limits: Number of Copies: See Section J Page Limitations: See Section J Appendix: See Section J Electronic File Size: <u>N/A</u>
9. Issued By: Sharon Kraft Contracting Officer DHHS/OS/OPHEP/ORDC 6700-B Rockledge Drive Room 4119 Bethesda, MD 20817		10. [X] ORDC reserves the right to make awards without discussion.
		11. Options: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
		12. Period of Performance: 5 years beginning on/about February 2006
13. Primary Point of Contact: Name : Brenda Brooks Phone: 301-435-2765 Fax: 301-402-0972 E-Mail: Brenda.Brooks@hhs.gov	14. Secondary Point of Contact: Name: Matthew Brown Phone: 301-451-3691 Fax: 301-402-0972 E-Mail: Matthew.Brown@hhs.gov	15. Collect Calls will not be accepted. Facsimile submissions are not acceptable.
16. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record", (See SECTION J – Attachments)		
17. DELIVERY ADDRESS INFORMATION		
18. Hand Delivery or Overnight Service: Brenda Brooks Contract Specialist HHS/OS/OPHEP/ORDC 6700-B Rockledge Drive, Room 4120 Bethesda, MD 20817		19. Packaging of Proposals: See Section J for proposals packaging instructions
21. The <u>Official Point of Receipt</u> for the purpose of determining timely delivery is the address provided in Block 18, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.		

Updated thru FAC 2001-27 (01/01/2005)

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SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against the factors in this section. The non-cost factors in order of importance are: technical, past performance, indemnification, and Small Disadvantaged Business (SDB) participation. In addition, prior to award, the Offeror's proposal must be considered acceptable for use of human subjects and animal welfare. All evaluation factors other than cost or price, when combined, are approximately equal to cost or price. Cost and price elements are of equal importance. Technical activities must connect directly to costs/prices in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the USG to consider award (s) to other than the lowest priced or highest technically rated Offeror. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Contract(s) will be awarded to the Offeror(s) whose proposal is considered to be the most advantageous to the Government, cost/price and other factors (identified below) considered. Each Offeror must submit a proposal that separately addresses evaluation criteria specified below as they relate to the statement of work and delivery requirements.

Intellectual Property

In order to be considered for award the Offeror shall provide documentation demonstrating unencumbered access to intellectual property necessary to fulfill their obligations under the contract. Initial proposals that do not include this documentation may be rejected. The U.S. GOVERNMENT expects and requires that the Offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials. Accordingly, the U.S. GOVERNMENT requires written evidence that the Offeror has secured access to such intellectual property, know-how and tangible materials to suitable cell culture and/or recombinant DNA technology unencumbered by legal or patent constraint

M.1. Mandatory Criteria for Eligibility

The offeror shall provide an index or dedicated section in the proposal that will direct reviewers to the specific area of the proposal that addresses a particular mandatory qualification.

- A. The following qualification criteria establish conditions that must be met prior to Proposal Review in order for your proposal to be considered any further for award.
 - 1. Documentation showing that the Offeror has developed a well-characterized MVA vaccine in single-dose vials containing up to 1×10^8 TCID₅₀ in frozen liquid suspension produced under cGMP using a process amenable to large-scale production.
 - 2. A plan for large-scale manufacturing, processing, and quality control of MVA vaccine.
 - 3. Non-clinical safety and efficacy and toxicology data in IND-enabling animal studies, and clinical safety and immunogenicity data in healthy subjects, at least through initiation of Phase 1 clinical trials.
 - 4. Demonstration that critical assays have been established for product release, stability testing, assessment of immune response in humans and animals, and potency evaluation.
 - 5. Documentation provided by the Offeror of cGMP and GLP compliance for all facilities to be involved in manufacturing of final drug product, and certification of the status of validation of all critical assays for in-process control, product release, immunogenicity, stability testing, and assessment of immune responses
- B. The additional Mandatory Qualification Criteria listed below establish conditions that MUST be met at the time of receipt of Final Proposal Revisions by all Offerors determined to be in the competitive range. If these conditions are not met at that time, your proposal will not be considered further for award: